

USSN: 10/749,907
Attorney Docket: I-2002.028 US C1
Response to Office Action of April 14, 2006

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REMARKS

Status of Claims

Claims 1, 4-6, 9-11 and 13-16 are currently pending, with claim 1 being the only independent claim.

Specification Objection

The specification has been amended to correct a typographical error in the reference to PCT/US03/31901. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this objection.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph— Enablement

Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. § 112, first paragraph for allegedly not being enabled by Applicants' specification. Office Action, page 3. Applicants respectfully disagree.

In response to Applicants' previous arguments to overcome this maintained rejection, the Examiner states that

... the Office recognizes that the claims are drawn to methods that use a specific antigenic class of Reoviruses. It is understood that the skilled artisan has the ability to carry out the claimed method steps. The question that the Office is raising, is whether Applicant has provided enough guidance that one of skill in the art would be able to propagate the avian reoviruses having the claimed capabilities. If given the reovirus(es) with all of the claimed properties, the step of propagating a virus that meets all the criteria is well within the ability of the skilled artisan. However, Applicant has only provided three examples of viruses having all of the claimed characteristics. While one would be able to propagate ERS 1037, ERS 060E and ERS 074, one would not be able to find other ERS of the same class without undue experimentation. Recall that the discovery of isolates ERS 1037, ERS 060E and ERS 074 was surprising and unexpected.

Office Action, pages 4-5. Based on this passage, it appears that the Examiner has rejected the

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claims on the grounds that Applicants' description of three ERS reovirus strains (ERS 1037, ERS 060E and ERS 074) does not enable claimed methods involving the defined antigenic class of avian reoviruses. Apparently, the Examiner alleges that the claims are not enabled because the skilled artisan would be required to undertake undue experimentation to find other ERS strains of the same class. Importantly, the Examiner agrees that the propagation method *is* enabled.

The rejection is improper, however, because it applies the wrong standard. Applicants' claims are directed to new and non-obvious methods employing a well known and well characterized class of avian reoviruses. As such, an inquiry as to whether the claims are enabled should not focus on whether Applicants have described every member of that class. Applicants' specification need not enable the antigenic class of reoviruses precisely because the class has already been described in U.S. Patent No. 6,951,650 (herein, "the '650 patent"). Enablement as to the antigenic class of reoviruses *per se* is not necessary.

The '650 patent describes the antigenic class of avian reovirus ERS isolates that i) are able to induce antiserum in an animal, which antiserum causes a reduction of the plaques formed by avian reovirus ERS deposited at the ECACC under accession no. 99011475, of at least 75% in a plaque reduction assay, and ii) positively reacts with polyclonal avian reovirus antiserum but not with monoclonal antibodies identified by accessions nos. 99011472, 99011473 and 99011474, samples of which are deposited at the ECACC. *See, e.g.*, Claim 1 of the '650 patent; *see also* Tables 2A, 2B and 3 describing several members of this antigenic class of reoviruses. Indeed, the '650 patent and its description of this antigenic class of avian reoviruses is incorporated by reference in Applicants' specification. *See* Applicants' Amendment and Reply Under 37 C.F.R. § 1.114, pages 2-3 and 7-8, filed March 1, 2006. Moreover, these very same class defining serological characteristics are included in Applicants' claims.

Applicants claims are directed to a new method (i.e., propagation without prior adaptation) that employs a well known and well characterized class of reoviruses. Although Applicants describe three novel and non-obvious members of this well known and well characterized class of reoviruses (i.e., strains ERS 1037, ERS 060E and ERS 074), Applicants' claims relate to the unexpected and surprising discovery that these and other members of this well known and well

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characterized class of reoviruses can be grown on Vero cells without prior adaptation.

The skilled artisan would not face any undue experimentation to practice the claimed invention. The serological tests to determine whether a particular viral strain is a member of the antigenic class are defined both in Applicants' specification and the '650 patent, which is wholly incorporated by reference. Guidance for the skilled artisan in the method of propagating the virus on Vero cells without prior adaptation is provided in Applicants' specification, for example, at page 13, lines 8-14 and in Example 1b on pages 16-17. Moreover, the Examiner has acknowledged that "Applicant has provided enough guidance that one of skill in the art would be able to propagate the avian reoviruses having the claimed capabilities." Office Action, pages 4-5. Because only routine testing (and no undue experimentation) is involved, the claims are enabled by the specification.

In summary, strains ERS 1037, ERS 060E and ERS 074 are members of a well known and well characterized antigenic class of avian reoviruses. While working with these strains, the inventors made the unexpected and surprising discovery that members of this well known and well defined class of antigenic reovirus class can be grown on Vero cells without prior adaptation. Hence, the claims are enabled by the specification and Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph— Written Description

Claims 1, 4-6, 9-11 and 13-16 are rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking an adequate written description. Office Action, pages 5. In response to Applicants' previous arguments to overcome this maintained rejection, the Examiner states the following:

While one would be able to propagate ERS 1037, ERS 060E and ERS 074, if handed to them, one would not be in possession of the larger genus of methods of making viruses of the antigenic class of reoviruses. . . .

Given the unexpectedness of the three strains to grow on Vero cells without prior adaptation, one of skill in the art would need more representatives of the genus of the ERS antigenic class. Access to three

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such strains has been given, ERS 1037, ERS 060E and ERS 074. If Applicant intends for the skilled artisan to first discover the strains of reovirus that have the claimed characteristics, and then use the discovered viruses in the instant method of propagation, then the claim is considered a reach-through claim that is inadequately described. Aside from ERS 1037, ERS 060E and ERS 074, the specification does not describe the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Office Action, page 7, lines 1-16. Applicants respectfully disagree with the rejection.

Applicants' unexpected and surprising discovery is that reovirus strains belonging to the well known and well characterized antigenic class of avian reoviruses grow on Vero cells without prior adaptation. As described above, the skilled artisan at the time of Applicants' invention was familiar with this antigenic class of reoviruses from the '650 patent. Applicants need not provide the skilled artisan with any greater description of the antigenic class, because this class was already known. Indeed, other members of this class have also already been described. See the '650 patent, figures 2A, 2B and 3. Moreover, Applicants' specification also wholly incorporates by reference the '650 patent, thereby providing a complete and adequate written description of the antigenic class of reovirus that may be used according to the claimed method.

The skilled artisan would fully appreciate that Applicants were in possession of the claimed invention at the time of filing. Indeed, discovery of this antigenic class is not required to practice the claimed method, and tests to verify whether a particular virus belongs to this class have already been adequately described. The description of the serological tests to determine whether a particular viral strain is a member of the antigenic class are defined both in Applicants' specification and the '650 patent, which is wholly incorporated by reference. A description of the method of propagating the virus on Vero cells without prior adaptation is provided in Applicants' specification, for example, at page 13, lines 8-14 and in Example 1b on pages 16-17. Moreover, the Examiner has acknowledged that "Applicant has provided enough guidance that one of skill in the art would be able to propagate the avian reoviruses having the claimed capabilities." Office Action, pages 4-5. Because all members of the same antigenic class are expected to

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behave the same way, Applicants have demonstrated in their application that a representative number of members of this class can grow on Vero cells without prior adaptation.

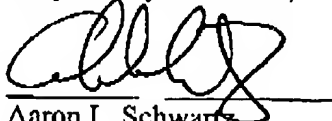
Because Applicants claimed method employs a well known and well characterized antigenic class of avian reoviruses, and because Applicants have actually shown that a representative number of members of this class can be practiced according to the claimed method, Applicants claims are supported by an adequate written description. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Conclusion

Applicants submit that this application is in condition for allowance, and request that it be allowed. Should the Examiner believe that a conference would be helpful in advancing the prosecution of this application, Examiner is invited to telephone Applicants' attorney at the number below.

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 02-2334.

Respectfully submitted,



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